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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,967	12/19/2001	David Bebbington	VPI/00-130-02	1802

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EXAMINER	
RAO, DEEPAK R	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,967	BEBBINGTON ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23-27 and 29-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-20,23-26,31,34,36 and 38* is/are allowed.

6)☒ Claim(s) *29,32,33,35,37 and 39* is/are rejected.

7)☒ Claim(s) *18, 21, 27, 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment filed on July 22, 2004.

Claims 1-21, 23-27 and 29-39 are pending in this application.

The following rejections are maintained:

Claims 29, 32-33, 35, 37 and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of specific disease such as colon cancer, breast cancer, stomach cancer, ovarian cancer or diabetes; inhibiting specific kinases, Aurora-2, GSK-3, Src, ERK-2 or AKT, does not reasonably provide enablement for a method of treating all other types of diseases of the instant claims; inhibiting the production of hyperphosphorylated Tau protein; or inhibiting the phosphorylation of β-catenin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments that claims 19, 20, 26, 27, 32-34 and 36 do not recite any diseases. As the specification provides test assays and data related to inhibiting of Aurora-2, GSK-3, Src, ERK-2 or AKT, the rejection of claims 19-21, 26-27, 34, 36 and 38 is hereby withdrawn.

Applicant further relies on the data related to inhibition of the kinases GSK-3, Src and argues that these are correlated with the diseases or disorders of the instant claims. Further, applicant urges that state of the art references Wiener et al., and Staley et al., show the correlation of Src inhibition with the treatment of colon and ovarian cancers. This activity has already been acknowledged and claim 23 drawn to the treatment of specific cancers has not been

rejected. Applicant has not provided sufficient evidence to meet the enablement requirements of the instant claims reciting method treating assorted diseases or disorders having diverse mechanisms and etiologies.

The instant claims cover disorder/diseases that are known to exist and those that may be discovered in the future, for which there is no enablement provided. Claims 35, 37 and 39, specifically recite 'a method of treatment of cancer' - no compound has ever been found to treat cancers of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a "silver bullet" is contrary to our present understanding of oncology. State of the art recognizes that "each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study". Different types of cancers affect different organs and have different methods of growth and harm to the body. Also see *In re Buting*, 163 USPQ 689 (CCPA 1969), wherein 'evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of the claims directed to disparate types of cancers'. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers or disorders caused by kinases generally.

There is no such agent which can treat 'viral diseases' generally. The recitation is extremely broad. Some of the viral diseases are caused by viruses, (e.g., HIV, common cold, measles, chicken pox, etc. - all the viral diseases are different one from the other. The nature of effect, origin, symptom, incubation, diagnosis, etc. is different for each one from the other. Applicant has not provided evidence of a single class of compounds that have been recognized in the state of the art, as therapeutically effective against viral diseases generally.

Further, 'neurodegenerative diseases' cover diverse disorders such as Alzheimer's disease, dementia, hereditary cerebellar ataxias, paraplegias, syringomyelia, phakomatoses, and much more. It is well known in the state of art that "some degenerative diseases are difficult to classify because they involve multiple anatomic locations". For example, Alzheimer's disease has traditionally been very difficult or impossible to prevent or even to treat effectively with chemotherapeutic agents.

Similarly, no evidence has been seen in the state of the art which establishes a single class of therapeutic agents as being effective against diverse diseases such as multiple sclerosis, AML, schizophrenia, baldness, cancer generally, autoimmune disease, cardiovascular disease, allergic disorder, hormone-related disease, etc. All of these diseases have diverse mechanisms and/or modes of action and different organs or body parts. There is no single therapeutic approach against all these diseases recognized in the state of the art.

(Only a few of the claimed diseases are discussed here to make the point of an insufficient disclosure, it does not definitely mean that the other diseases meet the enablement requirements). There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disease(s) or disorder(s) claimed herein.

Applicant further argues that 'sufficient direction and guidance has been provided in the specification to assess the activity of the compounds', however, as indicated above, the biological assays of the instant application cover inhibition of specific kinases, Aurora-2, GSK-3, Src, ERK-2 or AKT and there is no data related to inhibiting the production of hyperphosphorylated Tau protein or inhibiting the phosphorylation of β-catenin. When the best

efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, *In re Ferens*, 163 USPQ 609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs. Novo Nordisk*, 42 USPQ2nd 1001, 1006.

The following objections are necessitated by the amendment:

Claim Objections

Claims 18, 21, 27, 29 and 30 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Claim 18 multiply depends from claims 17 and 1-16 of which claim 17 is also a multiple dependent. Claims 21, 27, 29 and 30 depend from claim 18 and are therefore, included in the objection.

Allowable Subject Matter

Claims 1-20, 23-26, 31, 34, 36 and 38 are allowed, for the reasons already provided.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deepak Rao
Primary Examiner
Art Unit 1624

October 3, 2004